

Environmental Protection Agency

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§ 174.479 Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.

Residues of a pesticidal substance that is part of a plant-incorporated protectant from a sexually compatible plant are exempt from the requirement of a tolerance if all the following conditions are met:

(a) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.

[66 FR 37854, July 19, 2001]

Subpart X—List of Approved Inert Ingredients

§ 174.480 Scope and purpose.

This subpart lists the inert ingredients that have been exempted from FIFRA and FFDCA section 408 requirements and may be used in a plant-incorporated protectant listed in subpart B of this part.

§ 174.485 Inert ingredients from sexually compatible plant.

An inert ingredient, and residues of the inert ingredient, are exempt if all of the following conditions are met:

(a) The genetic material that encodes the inert ingredient or leads to the production of the inert ingredient is derived from a plant sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the inert ingredient are not present in food from the plant at levels that are injurious or deleterious to human health.

Subparts Y–Z [Reserved]

PART 176—TIME-LIMITED TOLERANCES FOR EMERGENCY EXEMPTIONS

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AUTHORITY: 21 U.S.C. 346a and 371.

SOURCE: 65 FR 64131, Oct. 25, 2000, unless otherwise noted.

§ 176.1 Scope and applicability.

This part describes the procedures and criteria under which EPA will establish time-limited tolerances and exemptions from the requirement of a tolerance for pesticide chemical residues associated with use of pesticides under emergency or crisis exemptions under FIFRA section 18. This part applies only to tolerances issued on the initiative of EPA as the result of the issuance of an emergency exemption or the declaration of a crisis exemption. This part does not cover time-limited tolerances in any other circumstances.

§ 176.3 Definitions.

The terms have the same meaning as in the Federal Insecticide, Fungicide, and Rodenticide Act section 2, and in the Federal Food, Drug, and Cosmetic Act section 201 and § 166.3 of this chapter. In addition, the following terms are defined for the purposes of this part.

Agency means the U.S. Environmental Protection Agency.

Applicant means any entity authorized under section 18 of FIFRA to request an emergency exemption that requests such an exemption under § 166.20 of this chapter, or issues a crisis exemption under § 166.40 of this chapter.

Crisis exemption means an exemption authorized under FIFRA section 18, in accordance with §§ 166.40 through 166.53 of this chapter.

Emergency exemption means a specific, quarantine, or public health exemption

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authorized under FIFRA section 18 and the regulations at §§166.20 through 166.35 of this chapter.

EPA means the U.S. Environmental Protection Agency.

FFDCA means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Tolerance means the maximum amount of a pesticide chemical residue that may lawfully be present in or on a raw agricultural commodity, or processed food, or animal feed, expressed as parts per million by weight of the pesticide chemical residue in the food or feed.

Tolerance exemption means a formal determination by the Agency pursuant to FFDCA section 408(c), 21 U.S.C. 346a(c), that no tolerance is needed for a given pesticide chemical residue in or on a particular food commodity. For purposes of this part, the term “tolerance” shall include an exemption from the requirement of a tolerance.

§ 176.5 Establishment of a time-limited tolerance or exemption.

EPA will establish a time-limited tolerance for pesticide chemical residues in or on raw or processed food or feed resulting from the use of a pesticide chemical, if EPA authorizes an emergency exemption or a crisis exemption. EPA will consider establishing such a tolerance only if an applicant acting under authority of FIFRA section 18 either has requested an emergency exemption, has stated its intention to issue a crisis exemption, or has issued a crisis exemption for a use that may result, directly or indirectly, in pesticide chemical residues in food or feed.

§ 176.7 Information needed to establish a tolerance.

(a) EPA will establish a time-limited tolerance only if EPA can determine that the tolerance is safe, that is, there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. EPA will base its determination upon data submitted by the applicant and other readily available data. If, taking into

account the limited duration and emergency nature of a section 18 application, and based on the available data the Agency cannot conclude that there is a reasonable certainty that no harm will result from the use proposed by the applicant or granted pursuant to a crisis exemption, EPA will not establish a tolerance.

(b) Data and other relevant information to support the establishment of a time-limited tolerance may be submitted by the applicant, or by any other person, in support of the time-limited tolerance. The applicant may also cite relevant data previously submitted to the Agency.

§ 176.9 Publication of a tolerance.

(a) If EPA issues an emergency exemption or crisis exemption under FIFRA section 18, and EPA concludes that the tolerance for residues resulting from use of the pesticide under the exemption will be safe, then EPA will establish the tolerance by publishing an amendment to 40 CFR part 180 in the FEDERAL REGISTER.

(b) A tolerance under this part may be established without prior publication of a proposed tolerance or comment period.

§ 176.11 Duration of a tolerance.

(a) Tolerances issued under this part will become effective upon publication in the FEDERAL REGISTER, unless otherwise specified by the Administrator.

(b) Unless extended, tolerances will automatically expire and be revoked, without further action by EPA, at the time set out in the final rule published in FEDERAL REGISTER.

(c) The Administrator may revoke a tolerance at any time if the Administrator determines that the tolerance is no longer safe.

§ 176.13 Modification of a time-limited tolerance.

If additional emergency or crisis exemptions are authorized that would extend use beyond the date originally authorized, or if EPA determines that the duration of a time-limited tolerance is insufficient to allow treated commodities to clear the channels of trade, EPA may modify the time-limited tolerance by publication of a final rule in

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the FEDERAL REGISTER. EPA will use the same criteria and procedures for modification as for establishing tolerances under this part.

§ 176.15 Effect of a tolerance.

The establishment of a tolerance under this part does not alter the requirement that any applicant comply with procedures established in part 166 of this chapter for emergency exemptions of FIFRA.

PART 177—ISSUANCE OF FOOD ADDITIVE REGULATIONS

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AUTHORITY: 21 U.S.C. 348, 371(a) 331(j); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50288, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 177.1 Scope and applicability.

(a) This part establishes procedures for the establishment, modification, or revocation by the Administrator of food additive regulations under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 348, for food additives which may result in pesticide residues in or on processed food or otherwise affect the characteristics of such food.

(b) Part 178 of this chapter contains procedures for filing objections and requests for hearings under FFDCA section 409(f) on food additive regulations or petition denials issued under this part. Part 179 of this chapter contains rules governing formal evidentiary hearings under FFDCA section 409(f).

(c) Part 180 of this chapter contains regulations establishing tolerances, or exemptions from the necessity for a tolerance, for pesticide residues on raw agricultural commodities under FFDCA section 408. If the use of a pesticide chemical in the production, storage, or transportation of a raw agricultural commodity (RAC) in conformity with such a tolerance or exemption results in the presence of a pesticide residue in or on processed food made from the RAC, FFDCA section 402(a)(2)(C) provides that such pesticide residue shall not be deemed unsafe for the purposes of FFDCA section 409 (despite the absence of a food additive regulation regarding such residue on the processed food) if the residue in or on the RAC has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the RAC. However, a food additive regulation would be required if the level of the pesticide residue in the processed food when ready to eat exceeded the level permitted in the "parent" RAC by the tolerance established under FFDCA section 408. In addition, if a pesticide residue in or on a processed food results from the application of a pesticide during or after processing, the food would be unsafe